IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF NICOLETTE HORBACH, M.D.

Nicolette Horbach, M.D. is a board-certified urogynecologist who has performed thousands of pelvic-floor surgeries, including those utilizing laser- and machine-cut mesh. She has taught medical students and residents, has conducted and published research, has authored textbook chapters and has been President of the American Urogynecologic Society. She stays abreast of the relevant literature in her field and has done so throughout her career. Based upon her review of medical literature and her extensive clinical experience, she seeks to offer general opinions on the diagnosis and treatment of pelvic-floor disorders, including the safe and efficacious use of the mesh products at issue in this litigation.

Despite this extensive experience, Plaintiffs argue that Dr. Horbach's opinions should be excluded in their entirety because of the manner in which Dr. Horbach cited the literature in her report. Then, ignoring those same citations and Dr. Horbach's sworn testimony, Plaintiffs argue that her opinions must be excluded because she had not seen a "reliance list" prior to her most recent deposition. But neither of these challenges make her opinions unscientific, unreliable, or subject to exclusion.

Plaintiffs' alternative challenges—allegedly based on qualifications only—fare no better. Dr. Horbach has extensive clinical, academic, and research experience. This experience, combined with her review of the scientific literature—both of which are reliable methodologies—makes her well qualified to give the opinions she seeks to give here. Plaintiffs' motion should be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. Horbach's Opinions Are Based on an Appropriate Methodology and Should be Admitted.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court in particular has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the risk/benefit profile of polypropylene mesh. *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *7 (S.D.W. Va. Apr. 24, 2015); *see also Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014); *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *32 (S.D.W. Va. Apr. 28, 2016).

Dr. Horbach has used this scientifically reliable methodology to come to her opinions about the safe and efficacious use of mesh here. Yet, Plaintiffs attempt to exclude her testimony in its entirety by arguing that her opinions are not supported by proper citations to the studies on which she relied. *See* Pls.' Mem. at 5-7 (Dkt. 2045). This argument fails, however, because nowhere do the Federal Rules of Civil Procedure require that an expert provide any sort of citation in her report. FED. R. CIV. P. 26(a)(1)(B). Rather, Rule 26 simply requires an expert to provide a complete statement of all her opinions, as well as the basis and reasons for those opinions. *Id.* Dr. Horbach did so here. *See generally* Ex. B to Pls.' Mot. (Dkt. 2044-2), Horbach

Report. As there is no uniform system of citation for expert reports championed by the Federal Rules—let alone a Federal Rule requiring that each study be cited after the expert's review of its data—any alleged issue pertaining to citations in Dr. Horbach's report cannot serve as a basis for excluding her testimony. If Plaintiffs had had any questions regarding the studies upon which Dr. Horbach based her opinions, they should have inquired into them during the course of her numerous depositions. But they did not, and the Court should not reward Plaintiffs now by excluding her testimony simply because they failed to ask about the literature on which Dr. Horbach relied.

Alternatively, and ignoring her so-called faulty citations, Plaintiffs argue that Dr. Horbach's testimony should be excluded because at her latest deposition she stated that she did not review a reliance list. Pls.' Mem. at 3-7 (Dkt. 2045). Plaintiffs' argument fails to take into account that, although Dr. Horbach may not have reviewed *the list that identified the materials she reviewed*, she has testified that she reviewed *the actual materials themselves*. Ex. E to Pls.' Mot. (Dkt. 2044-5), Horbach 3/25/16 Dep. Tr. 15:1-12 ("I've looked at the bulk of the[] [materials]."). Plaintiffs' argument further ignores that Dr. Horbach has testified at least four times in this litigation and has each time produced an expert report along with a reliance list. *See generally id.*; Ex. 1, Horbach 8/21/13 Dep. Tr.; Ex. G to Pls.' Mot. (Dkt. 2044-7), Horbach 11/22/13 Dep. Tr.; Ex. F to Pls.' Mot. (Dkt. 2044-6), Horbach 12/23/15 Dep. Tr.

The opinions expressed in her latest report simply build off those previous lists of materials. In each of her previous depositions, she testified that she read all the literature contained within her reliance list. For example, during her November 2013 deposition, she testified that she reviewed all of the literature enumerated in the reliance list for her general report:

Q. Let's go to the section titled "Literature." Have you read every one of those articles that are listed?

A. At some point either prior to the report or in the past as part of other educational endeavors.

. . .

Q. Did you rely on all these articles in writing your expert report, or were they simply put on the list just to be over inclusive?

. . .

A. . . . I have read all of these in creating my expert report in addition to my, you know, clinical experience. This is part and parcel of my clinical expertise.

Q. Are all of these articles listed in the literature section significant to you as a basis for the opinions you hold in this case?

A. I would say yes in that either the article may substantiate my opinion, the article may be contra to my opinion, although I may disagree with parts of the article, but these were all part of what I have read and reviewed prior to the time of writing my general report. So they—I can't tell you, you know—I'll just say prior to writing the report, these have all been reviewed, so they all are a basis for my opinion.

Ex. G to Pls.' Mot. (Dkt. 2044-7), Horbach 11/22/13 Dep. Tr. 18:18-24, 19:5-7, 19:9-13, 19:15-20:2. She made similar mention of this during her December 2015 deposition:

Q. Doctor, you drafted your own report, correct?

A. Yes.

Q. Okay. And is it fair to say that if I want to—if I wanted to know the materials you relied upon in formulating your opinions, that they would be contained within the body of your expert report?

> A. Most likely, yes. I think, yes, most likely. I mean, there is a lot of other material obviously over—because of my training, education, what I see on a day-to-day basis that I used in generating my report that isn't necessarily specifically referenced in that area of the report.

Ex. F to Pls.' Mot. (Dkt. 2044-6), Horbach 12/23/15 Dep. Tr. 67:17-68:3. Ultimately, given that Dr. Horbach has reviewed all the materials used to form the opinions expressed in her expert report, the fact that she did not review a list of those materials is inconsequential and does nothing to render her methodology or opinions unreliable.

Lastly, Plaintiffs' argument that Dr. Horbach's testimony should be excluded because this reliance list is the "sole basis of her expert report" (Pls.' Mem. at 4 (Dkt. 2045)) is likewise unavailing. Plaintiffs cite no support for this argument. Nor can they, as the claim is simply untrue. Dr. Horbach sets forth the numerous other bases for her opinions—*e.g.*, "[her] education, [her] knowledge and review of the medical literature, [her] training, and [her] extensive clinical and surgical experience gained over nearly 30 years of patient care"—in her expert report. Ex. B to Pls. Mot. (Dkt. 2044-2), Horbach Report at 3-4.

In sum, Dr. Horbach reached her opinions using a well-recognized, reliable, and appropriate methodology, and sufficiently detailed her opinions along with their bases in her report. The Court should deny Plaintiffs' motion.

II. None of the Opinions Expressed by Dr. Horbach Are Outside Her Areas of Expertise.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem*, 57 F. Supp. 3d at 714. This Court in particular has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the safety and efficacy of polypropylene mesh products. *See Tyree*, 54 F. Supp. 3d at 585 (finding that a urologist with extensive clinical

experience and relying on peer-reviewed literature could opine on the safety and efficacy of polypropylene mesh products).

A. Dr. Horbach is qualified to opine on the differences between laser- and machine-cut mesh.

Based on her clinical experience alone, Dr. Horbach has the necessary qualifications to opine that there is no difference between laser- and machine-cut mesh.[1] Specifically, Dr. Horbach is a urogynecologist who sees thousands of patients per year and has performed thousands of pelvic floor operations. Ex. B to Pls.' Mot. (Dkt. 2044-2), Horbach Report at 3. Further, she specifically testified that over the course of her 39-year practice, she has performed multiple surgeries using laser-cut mesh and is familiar with the product:

> Q. How many laser-cut TVT Retropubic meshes have you implanted?
>
> A. I can't recall specifically. *I mean, I know I've certainly implanted laser-cut Ethicon midurethral slings, because that's what the Exact* is, but I don't remember in specific Retropubic whether I was using primarily—I mean, obviously primarily machine-cut in the beginning, but I don't recall how many I have done in that transition time period when it became an option of laser-cut versus mechanical-cut.

Ex. F to Pls.' Mot. (Dkt. 2044-6), Horbach 12/23/15 Dep. Tr. 92:14-24 (emphasis added).

Based on her clinical experience with laser-cut mesh, Dr. Horbach has formed the opinion that there are no differences between it and machine-cut mesh. Specifically, she sees no differences between the two during implantation:

[1] Plaintiffs' argument that Dr. Horbach is unqualified to testify as to the differences between laser- and machine-cut mesh because she has no clinical experience with laser-cut mesh is misguided. This argument is nothing more than an attempt to mislead the Court. Indeed, Plaintiffs omit critical portions of Dr. Horbach's testimony—specifically lines 93:10-19—which clarifies that she was simply noting that she did not know whether she had performed a laser-cut TVT Retropubic versus a machine-cut TVT Retropubic procedure. Ex. F to Pls.' Mot. (Dkt. 2044-6), Horbach 12/23/15 Dep. Tr. 93:7-22.

> Q. Okay. Do you have any opinions relating to the differences between mechanical-cut and laser-cut TVT Retropubic mesh?
>
> A. In my experience—excuse me. In my experience clinically I don't see a difference in how the two meshes behave either during implantation or subsequent to implantation in the patient.

Id. at 92:7-13. She has also testified that there is no difference between the two with respect to stiffness:

> Q. Is the laser-cut mesh stiffer than the mechanical-cut mesh?
>
> A. From a—from a tactile standpoint, you don't really feel a lot of difference with it. I would sort of—if you were to give them to me, I wouldn't cause—I wouldn't determine that stiffness was the difference between the two.

Ex. E to Pls.' Mot. (Dkt. 2044-5), Horbach 3/25/16 Dep. Tr. 52:8-14.

Dr. Horbach's review of relevant medical literature also supports her opinion that there is no difference between laser- and machine-cut mesh. Ex. B to Pls.' Mot. (Dkt. 2044-2), Horbach Report at 64-65. In fact, as Dr. Horbach pointed out in her report, there are no studies that indicate laser-cut mesh is safer or more effective than machine-cut mesh. *Id.* (noting that the "difference between mechanically cut mesh and laser-cut mesh is simply aesthetic and based on surgeon preference").

It is ironic that Plaintiffs seek to exclude her testimony because she has not done scientific testing of laser-cut mesh versus machine-cut mesh, and relies solely on her experience. Plaintiffs' experts have also done no testing, and they also have no experience, because they do not implant mesh. This would thus be a ground to exclude the issue of laser-cut versus machine-cut mesh in its entirety, which is what the court should do if it precludes Dr. Horbach from testifying on this issue.

Accordingly, if the issue remains in the case, the Court should not preclude Dr. Horbach from opining on the differences between laser- and machine-cut mesh.

B. Dr. Horbach is qualified to testify that she has never seen degradation of explanted mesh in her clinical practice.

Although Plaintiffs argue that Dr. Horbach is not a pathologist, that fact is irrelevant because she is not offering any opinions regarding the pathology of explanted mesh. In fact, the word "pathology" does not appear anywhere within Dr. Horbach's 79-page report. *See generally* Ex. B to Pls.' Mot. (Dkt. 2044-2), Horbach Report. Rather, Dr. Horbach is offering opinions regarding the alleged degradation of mesh—a condition she has not really encountered throughout her 30 years of clinical experience:

> Q. Okay. Do you have an opinion regarding whether or not the mesh in the TVT degrades in any amount within a woman's pelvis?
>
> A. In my experience and my review of the literature I do not think that degradation is a significant or clinical[ly] relevant issue within a patient.
>
> Q. Let me just clarify. It sounds like you're not saying there is not some degree of degradation; you're just saying it's not clinically significant. Is that fair?
>
> A. No, I'm not saying it's not—definitely not clinically significant, and trying to determine if something is a nonclinically significant degradation is difficult to do. I think that the—
>
> Q. Okay.
>
> A. —studies—I'm not done. I think that the studies that have looked at degradation, many of them have not shown degradation to occur in explanted specimens, and the difficulty is, as soon as you explant a specimen, you are creating artifact in any evaluation of that specimen that can be related to just the process of surgically implanting and/or removing.

Ex. E to Pls.' Mot. (Dkt. 2044-5), Horbach 3/25/16 Dep. Tr. 52:19-53:19. This is simply stating what is undisputedly true. The "degradation" about which plaintiffs complain is, at best, one micron thick, is not observable with the naked eye, is not observable under an ordinary microscope, and has never been shown by testing to have clinical consequences. Absent proof to the contrary, there is no basis for Plaintiffs to object to her testimony in this regard.

As a board-certified physician in Obstetrics and Gynecology with extensive surgical experience, along with her knowledge of the relevant medical literature, Dr. Horbach is qualified to testify about clinical experience with explanted mesh. Ex. H to Pls.' Mot. (Dkt. 2044-8), Horbach Curriculum Vitae at 3-4; Ex. B to Pls.' Mot. (Dkt. 2044-2), Horbach Report at 3. This Court has held that this experience and background is sufficient. *See Tyree*, 54 F. Supp. 3d at 585 (finding urologist with extensive pelvic-floor surgical experience qualified to offer opinions about mesh degradation even though urologist was not a pathologist).

C. Dr. Horbach is qualified to opine on the contents of the TVT Retropubic IFUs and DFUs.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger*, 2015 WL 1887222, at *15. A urogynecologist, in particular, is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues).

Dr. Horbach seeks to offer such an opinion here. Based on her clinical perspective and her review of the literature, she seeks to testify how clinicians would interpret the IFUs and what problems may arise if the IFU is interpreted incorrectly. *See, e.g.*, Ex. B to Pls.' Mot. (Dkt. 2044-

2), Horbach Report at 47-49; Ex. G to Pls.' Mot. (Dkt. 2044-7), Horbach 11/22/13 Dep. Tr. 127:18-128:1 (noting that Dr. Horbach's opinions regarding the Ethicon IFU centers around her reaction to the warnings contained in the IFU); Ex. F to Pls.' Mot. (Dkt. 2044-6), Horbach 12/23/15 Dep. Tr. 55:23-59:19 (explaining that any mesh-related surgery should be performed by a surgeon who has an understanding of the surgery and that the IFU contains a warning to that extent).[2] She is qualified to give these opinions.

Plaintiffs' argument that Dr. Horbach is unqualified to offer opinions pertaining to the contents of the IFUs and DFUs because "she has never worked on device labeling" and has no "experience . . . drafting medical device IFUs" is thus inapposite. Pls.' Mem. (Dkt. 2045) at 11-13. No one is suggesting that Dr. Horbach is an FDA regulatory expert. Nor does she need to be, as her opinions speak only to how clinicians would interpret the IFUs, and what problems may arise if the IFU is interpreted incorrectly. *See, e.g.*, Ex. B to Pls.' Mot. (Dkt. 2044-2), Horbach Report at 47-49; Ex. G to Pls.' Mot. (Dkt. 2044-7), Horbach 11/22/13 Dep. Tr. 127:18-128:1 (noting that Dr. Horbach's opinions regarding the Ethicon IFU centers around her reaction to the warnings contained in the IFU); Ex. F to Pls.' Mot. (Dkt. 2044-6), Horbach 12/23/15 Dep. Tr. 55:23-59:19 (explaining that any mesh-related surgery should be performed by a surgeon who has an understanding of the surgery and that the IFU contains a warning to that extent).

Given Dr. Horbach's substantial clinical experience and her review of the literature, she is qualified to opine on how clinicians would interpret the IFU and this opinion is based on a reliable methodology.

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[2] Dr. Horbach's opinion is consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (information may be omitted from labeling for prescription device "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.").

D. Dr. Horbach is qualified to testify as to the material characteristics of in polypropylene mesh.

An expert need not be a "material scientist, biochemist, or biomedical engineer" or have performed "mechanical or chemical testing of mesh products" to opine on "mesh degradation, mesh contraction, and mesh migration." *Tyree*, 54 F. Supp. 3d at 528 (allowing Richard W. Trepeta, M.D. to testify as to mesh degradation despite having no background in biochemistry).

Plaintiffs' nonetheless take issue with Dr. Horbach's opinions on the material characteristics of polypropylene mesh because she is not a biochemist. However, Dr. Horbach is not offering opinions as to the material aspects of Ethicon mesh; she is only opining on the alleged degradation of mesh. *See generally* Ex. B to Pls.' Mot. (Dkt. 2044-2), Horbach Report.

Dr. Horbach's analysis of the literature, *see id.* at 18-38, 53-57, 65-78, as well as her extensive experience with midurethral slings and other incontinence procedures make her eminently qualified to provide opinions regarding whether TVT is safe and suitable for use as a permanent implant in the female pelvis and whether it degrades or contracts. *See id.* at 3 (noting that Dr. Horbach has "extensive experience with native tissue repairs, biologic grafts (autographs, allografts, and xenografts) and a wide range of monofilament and multifilament synthetic mesh materials including polypropylene, polytetrafluorethylene, polyester, and polyethylene grafts" and that she has performed thousands of pelvic floor procedures using various products, including TVT). Nothing under *Daubert* precludes these opinions.

E. There is no basis to exclude unidentified opinions.

Plaintiffs in the final alternative wrongly seek to exclude all opinions "that do not provide identifying source information." Pls.' Mem. (Dkt. 2045) at 15. Plaintiffs do not say what opinions these are. Plaintiffs have deposed Dr. Horbach on numerous occasions and have had

more than enough opportunity to ask her to "identify" her sources. There is no merit to this request.

CONCLUSION

For the foregoing reasons, Ethicon asks this Court to deny Plaintiffs' motion and permit Dr. Horbach to give general-causation opinion testimony as set forth above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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